

HFA-305

Approval Date: JUL 13 2004

**FREEDOM OF INFORMATION SUMMARY**  
**SUPPLEMENTAL ABBREVIATED NEW ANIMAL**  
**DRUG APPLICATION (ANADA)**

**ANADA 200-066**

**AGRIMYCIN 166**  
**(oxytetracycline hydrochloride)**

**Additional packet size (9.87 oz [280 g]), change of strength of  
oxytetracycline HCl, new trade name and change in inactive  
ingredients**

**Sponsored by:**

**Agri Laboratories, Ltd.**  
**P.O. Box 3103**  
**St. Joseph, MO 64503**

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## FREEDOM OF INFORMATION SUMMARY

**1. General Information:**

- a. File Number: ANADA 200-066
- b. Sponsor: Agri Laboratories, Ltd.  
P.O. Box 3103  
St. Joseph, MO 64503  
  
Drug Labeler Code: 057561
- c. Established Name: Oxytetracycline hydrochloride
- d. Proprietary Name: AGRIMYCIN 166
- e. Dosage Form: Soluble Powder
- f. How Supplied: 9.87 oz [280 g] packet and 40 packets in a pail
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each 2.73 grams of powder contains 1 gram of oxytetracycline hydrochloride (packet: 9.87 oz [280 g]).
- i. Route of Administration: Oral
- j. Species/Class: Chickens, turkeys, & swine
- k. Recommended Dosage: Swine-10 mg per pound body weight daily for five days.  
Chickens-200-800 mg per gallon  
Turkeys-200-400 mg per gallon, for growing turkeys-25 mg per pound body weight daily
- l. Pharmacological Category: Antibacterial
- m. Indications: Chickens: 200 to 400 mg per gallon for control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to oxytetracycline.

400 to 800 mg per gallon for control of respiratory disease (CRD) and air sac infections caused by *Mycoplasma gallisepticum* and *Escherichia coli*, susceptible to oxytetracycline.

400 to 800 mg per gallon for control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline.

Turkeys: 200 to 400 mg per gallon for control of Hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

400 mg per gallon for control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to oxytetracycline.

25 mg/lb body weight in growing turkeys for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.

Swine: 10 mg/lb body weight for the control and treatment of the following diseases in swine – Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline. Bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline. For breeding swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona* susceptible to oxytetracycline.

n. Pioneer product:

OXYTET Soluble; oxytetracycline hydrochloride; NADA 130-435; Alpha, Inc.

o. Effect of the Supplement:

The supplement provides for approval of an additional packet size, 9.87 oz [280 g], a different trade name, an alternate concentration of active ingredient and a change in the inactive ingredients in the finished dosage form.

## **2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug

(pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Agri Laboratories, Ltd., was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product AGRIMYCIN-166. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredients. The pioneer product, OXYTET Soluble (oxytetracycline hydrochloride), sponsored by Alpharma, Inc., NADA 130-435, was approved on August 18, 1985.

### **3. HUMAN SAFETY:**

#### **• Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. Tolerances for the sums of residues of tetracycline, including oxytetracycline in tissues of swine, chickens, and turkeys are as follows: (a) 2 parts per million (ppm) in muscle; (b) 6 ppm in liver; (c) 12 ppm in fat and kidneys (21 CFR § 556.150). The acceptable daily intake for residues of oxytetracycline is 25 micrograms per kilogram of body weight per day.

#### **• Withdrawal Times:**

The assigned withdrawal period is the same as the pioneer product. Based on the limitations in 21 CFR § 520.1660d, a zero day withdrawal time is required for chickens, turkeys, and swine.

#### **• Regulatory Methods for Residues:**

The regulatory analytical method for the determination of residue of oxytetracycline is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method is found in *Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols*, Revised October, 1968, Reprinted December, 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

### **4. AGENCY CONCLUSIONS:**

This supplemental ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that AGRIMYCIN-166 (oxytetracycline hydrochloride), when used under its proposed conditions of use, is safe and effective for its labeled indications.

Mfd. for: Agri Laboratories, Ltd.  
St. Joseph, Missouri - 64503

**DIRECTIONS FOR USE:** Mix fresh solutions daily - Use as sole source of drinking water - Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. If improvement is not noted within 24 to 48 hours, consult a poultry veterinarian or poultry diagnostic laboratory. As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. Note: The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animals, feed consumption rate, and the environmental temperature and humidity, each of which affects water consumption.

**CAUTION:** USE AS SOLE SOURCE OF OXYTETRACYCLINE - NOT TO BE USED FOR MORE THAN 5 CONSECUTIVE DAYS IN SWINE AND 14 CONSECUTIVE DAYS IN CHICKENS AND TURKEYS.

➤ **WARNING:** DO NOT FEED TO BIRDS PRODUCING EGGS FOR HUMAN CONSUMPTION. DISCONTINUE TREATMENT OF CHICKENS, TURKEYS AND SWINE 0 DAYS PRIOR TO SLAUGHTER

Issue Date 0403

**RECOMMENDED STORAGE:** STORE BELOW 77°F (25°C)  
**FOR USE IN DRINKING WATER ONLY - NOT FOR USE IN LIQUID FEED SUPPLEMENTS**

# AGRIMYCIN® 166



## Oxytetracycline Hydrochloride Soluble Powder

antibiotic for control of specific diseases in poultry and swine

This packet contains 102.4 grams of Oxytetracycline HCl and will make:  
512 gallons (1938 L) containing 200 mg Oxytetracycline HCl per gallon  
256 gallons (969 L) containing 400 mg Oxytetracycline HCl per gallon  
128 gallons (484 L) containing 800 mg Oxytetracycline HCl per gallon

This packet will treat 10,240 pounds of swine

FOR USE IN ANIMALS ONLY

KEEP OUT OF REACH OF CHILDREN

ANADA 200-066, Approved by FDA

**NET WEIGHT 9.87 oz (280g)**

# Agrilabs®

### MIXING INSTRUCTIONS FOR WATER MEDICATION - CHICKENS - TURKEYS - SWINE

**DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS** - Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

	DISEASE	TREATMENT LEVEL	PACKS/GAL STOCK SOL
CHICKENS	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200-400 mg	1/4-1/2 (70-140g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400-800 mg	1/2-1 (140-280g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400-800 mg	1/2-1 (140-280g)
TURKEYS	Control of hexamiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline.	200-400 mg	1/4-1/2 (70-140g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to oxytetracycline.	400 mg	1/2 (140g)
	GROWING TURKEYS - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis) susceptible to oxytetracycline.	25 mg/lb. body weight	Varies with age & water consumption
SWINE	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE: Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb. body weight	Varies with age & water consumption

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# MIXING INSTRUCTIONS FOR WATER MEDICATION

## CHICKENS — TURKEYS — SWINE

**DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS**—Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

	DISEASE	TREATMENT LEVEL	PACKS/GAL. STOCK SOL.
CHICKENS	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	¼-½ (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	½-1 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	½-1 (140-280 g)
TURKEYS	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline.	200 - 400 mg	¼-½ (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to oxytetracycline.	400 mg	½ (140 g)
SWINE	GROWING TURKEYS—Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to oxytetracycline.	25 mg/lb. body weight	Varies with age & water consumption
	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE: Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb. body weight	Varies with age & water consumption

MFD. FOR: AGRI LABORATORIES, LTD.  
 St. Joseph, MO 64503

# AGRIMYCIN®-166

## Oxytetracycline Hydrochloride Soluble Powder

**antibiotic** for control of specific diseases in poultry and swine

Each packet contains 102.4 grams of oxytetracycline HCl and will make:  
 512 gallons (1938 L) containing 200 mg oxytetracycline HCl per gallon  
 256 gallons (969 L) containing 400 mg oxytetracycline HCl per gallon  
 128 gallons (484 L) containing 800 mg oxytetracycline HCl per gallon

Each packet will treat 10,240 pounds of swine.

ANADA 200-066, Approved by FDA

**NET CONTENTS: 40 PACKETS**  
 Each containing 9.87 oz (280 g)

# AgriLabs®

**DIRECTIONS FOR USE:** Mix fresh solutions daily - Use as sole source of drinking water - Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers.

If improvement is not noted within 24 to 48 hours, consult a poultry veterinarian or poultry diagnostic laboratory. As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys.

**Note:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animals, feed consumption rate, and the environmental temperature and humidity, each of which affects water consumption.

**CAUTION:** USE AS SOLE SOURCE OF OXYTETRACYCLINE—NOT TO BE USED FOR MORE THAN 5 CONSECUTIVE DAYS IN SWINE AND 14 CONSECUTIVE DAYS IN CHICKENS AND TURKEYS.

**WARNING:** DO NOT FEED TO BIRDS PRODUCING EGGS FOR HUMAN CONSUMPTION. DISCONTINUE TREATMENT OF CHICKENS, TURKEYS AND SWINE 0 DAYS PRIOR TO SLAUGHTER.

**RECOMMENDED STORAGE:** STORE BELOW 77°F(25°C)

**FOR USE IN DRINKING WATER ONLY—**  
**NOT FOR USE IN LIQUID FEED SUPPLEMENTS**

**FOR USE IN ANIMALS ONLY**  
**KEEP OUT OF REACH OF CHILDREN**

Rev. 0403



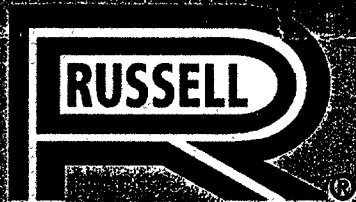
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Exp. Date



**MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS — TURKEYS — SWINE** Dosage and indications for use in water proportioners - Add the following amount to 1 gallon of stock solution when proportioner is set to meter at the rate of 1 oz per gallon.

	Disease	Treatment Level	Pack/Gallon Stock
C H I C K E N S	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	¼-½ (70-140g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline	400 - 800 mg	½-1 (140-280g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline	400 - 800 mg	½-1 (140-280g)
T U R K E Y S	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	¼-½ (70-140g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	½ (140g)
	GROWING TURKEYS — Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline	25 mg/lb body weight	Varies with age & water consumption
S W I N E	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE — Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline FOR BREEDING SWINE Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline	10 mg/lb body weight	Varies with age & water consumption



Oxytetracycline  
hydrochloride

Antibiotic

Oxytel  
Soluble

## OXYTETRACYCLINE HCl

This packet contains 102.4 g of oxytetracycline HCl and will make:

- 512 gallons (1936 liters) containing 200 mg oxytetracycline HCl per gallon
- 128 gallons (484 liters) containing 800 mg oxytetracycline HCl per gallon

This packet will treat 10,240 lbs of swine.

## ANTIBIOTIC

### RECOMMENDED PACKET STORAGE CONDITIONS:

Store below 77°F (25°C)

See back panel for instructions.

Take Time



Observe Label Directions

For Use in Drinking Water Only

Not For Use in Liquid Type B Medicated Feeds

Keep Out of Reach of Children

Net Weight

9.87 oz (280 g)

Restricted Drug. Use Only as Directed (California).



Alpharma Inc.  
One Executive Drive, Fort Lee, New Jersey 07024

List #2201

AHF-031 0211

NADA #130-435, Approved by FDA

Oxytel is a trademark of Alpharma Inc.

**DIRECTIONS FOR USE:** Mix fresh solutions daily. Use as the sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink 1 gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use as the sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

**WARNING - Do not feed to birds producing eggs for human consumption. LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.**